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09/475,768	12/30/1999	PINAKI RAY	03764.P002	6849

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EXAMINER	
WILLIAMS, CATHERINE SERKE	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/475,768	RAY, PINAKI	
	Examiner	Art Unit	
	Catherine S. Williams	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2004* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 48-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 48-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 12-13 and 48-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boddie (US Pat# 4,192,302) in view of Aigner (US Pat# 4,540,402).

Boddie, in general, discloses a system for fluid isolation in a biological mass having an upstream channel and a downstream channel. The system includes a delivery occlusion conduit that is positioned adjacent the upstream channel, a collection conduit that is positioned adjacent the downstream channel. The perfusion fluid is pumped (pressure device) through the delivery conduit and reclaimed by the collection conduit. The fluid may be a chemotherapeutic agent.

The device has lumens for fluid flow either into or out of the body and is therefore considered capable of being used at any time point, including during diastole and systole. The device having catheters (delivery and collection) sized to enter into blood vessels of the body is thereby capable of being percutaneously positioned via a translumenal route from a first externally accessible channel of a patient. See figure 3.

Specifically, figure 1 of Boddie outlines flow to and from the major organ systems in the body. It is commonly understood that vessels that flow into an organ are considered being upstream to the organ and conversely vessels taking flow away from are considered downstream to the organ. Looking at figure 1, one can clearly see that the hepatic artery and portal vein are

upstream vessels that flow into the liver and while not labeled the hepatic veins are the vessels that receive flow from the liver and return the flow eventually to the heart via the inferior vena cava.

With the above flow scheme in mind, attention is drawn to figure 3 of Boddie. The hepatic artery and portal vein (upstream vessels) are labeled and, as shown, receive branches 35 and 36 of catheter 34. Catheter 34 (delivery conduit) and branches 35 and 36 deliver chemotherapy agents 20 to the liver via these upstream channels. Ligatures T1 and T2 conformably engage and releasably hold (see 3: 30-31) the first branch catheter 35 to the hepatic artery and the second branch catheter 36 to the portal vein, respectively. Each branch 35 and 36 has an opening distal to the ligatures. During placement of the branches and before the ligatures are in place, fluid flow will occur past the catheter branches. Catheter 34 and branches 35 and 36 have a length dimension suitable to be positioned from a first externally accessible channel of a patient (hepatic artery and portal vein are externally accessed by branches 35 and 36 of catheter 34 the proximal end of which resides outside of the patient's body – see figure 3) and then they proceed by way of a translumenal route (see dashed lines indicating catheter branches inside the vessels). Regarding the term percutaneous the prior art meets this claim term since at some point during the procedure an incision was made in the patient's skin to access the vessels.

Next, Boddie generally refers to means 40 "for selectively isolating the patient's cancer-involved liver". See 2:32-34 of Boddie. Catheter 41 in general shunts blood flow in the inferior vena cava from below the liver to above the liver (see ligatures T3 and T4) via outlet 43 of catheter 41 positioned in the right atrium of the heart. The important aspect of means 40 is that the region of the inferior vena cava between the ligatures T3 and T4 (collection seals) isolates the

flow from the hepatic veins (area of vessel just before T4). Catheter 41 (collection conduit) has opening 44 that collects flow from the isolated region (between ligature T3 and T4) of the inferior vena cava (downstream channel) and returns the flow from the liver to the external flow path. Catheter 41 has a length dimension suitable to be positioned from a first externally accessible channel of a patient (inferior vena cava – see opening in figure 3) and then it proceeds by way of a translumenal route (see dashed lines indicating catheter inside the vessel). Regarding the term percutaneous the prior art meets this claim term since at some point during the procedure an incision was made in the patient's skin to access the vessel(s).

Boddie meets the claim limitations as described above but fails to include the deliver/collection conduits having collection seals having a dimension to occlude such as elastomeric balloons and the catheters having three lumens.

At the time of the invention, it would have been obvious to substitute balloons for the ligatures of Boddie. Externally mounted balloons on catheter shafts are well known in the catheter art to effectively, less-invasively and safely occlude blood vessels. This is clearly taught by Aigner where the fourth embodiment is designed with a mounted balloon (8) on the front end of the catheter instead of using a ligature. See 3:1-2. "Since making the ligature around the point of the splint catheter is often difficult due to the close proximity of the heart, a preferred embodiment of the invention displays an inflatable balloon in the area of the catheter point; the balloon is mounted from the outside and can be blown up by means of a feed line, **thus creating a seal** within the vessel and making the external ligature unnecessary." [emphasis added] See 4:42-52. The feed line has a lumen (9) with a connection port (10 – seal control mechanism) and

is thereby configured to expand and contract the balloon at any time point desired including during diastole and systole, respectively.

Using the same rationale as the Aigner reference, one could obviously reason that when in close proximity of other organs, i.e. the liver as in the case of the Boddie reference, one would want to take the same level of care and use an inflatable balloon in order to provide an occluding device that enhanced the safety to the patient by preventing undue organ damage.

At the time of the invention, it would have been obvious to incorporate two additional lumens into the catheter since the Boddie reference itself teaches a multi-lumen catheter (i.e. the collection conduit (9)) that has fluid, guidewire and inflation lumens. Having these three lumens in one catheter is common in the art since a balloon catheter if being used to transfer fluids will necessitate at least two lumens (i.e. one for fluid and one to inflate the balloon). Additionally, the procedure of using a guidewire to introduce a catheter into the body is also well known in the art and standard practice to ensure proper and safe placement of the device. The motivation for incorporating an inflation lumen and a guidewire lumen would have been to enable the use of a balloon (see paragraph above) and a guidewire thereby providing a device that has been enhanced for safety of the patient both during placement and use.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boddie in view of Aigner.

Boddie in view of Aigner meet the claim limitations as described above but fail to include the biological mass being the human heart. At the time of the invention, it would have been obvious to use the invention of Boddie to isolate and perfuse the human heart during

procedures such as bypass where the delivery conduit would be positioned into the aorta and the collection conduit would be positioned into the coronary sinus.

Further the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently that the prior art device, the claimed device was not patentably distinct from the prior art device.

Claims 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boddie in view of Aigner in further view of Sterman et al (USPN 5,452,733).

Boddie in view of Aigner meets the claim limitations as described above but fails to include the biological mass being the heart, the first externally accessible channel being a femoral artery and a second externally accessible channel being the jugular vein.

However, Sterman discloses a method for accessing the heart and includes placing a catheter into the aorta via the femoral artery and placing a catheter into the coronary sinus via the jugular vein. See Detailed Description paragraphs 14,15 and 18. This double placement of occlusion balloon catheters enable either antegrade or retrograde fluid delivery with a minimally invasive approach of accessing the heart. See Summary.

At the time of the invention it would have been obvious to incorporate the method and route of balloon catheter placement into the invention of Boddie in view of Aigner. The motivation for selecting the heart as the biological mass would have been since heart bypass procedures require devices having the structure of the invention of Boddie in view of Aigner and would have been done in order to use the device in an additional application that utilizes its

intended function. Additionally, the motivation for the incorporation of the vessel insertion as taught by Sterman would have been in order to provide a minimally invasive procedure (as taught by Sterman, above) to enhance the safety to the patient.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970.

The examiner can normally be reached on Monday - Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams
November 23, 2004

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